K014073

FEB 1 3 2002

Portex, Inc.
10 Bowman Drive
Keene NH 03431-0724 USA
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K: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY:

COMPANY INFORMATION:

Portex, Inc.
10 Bowman Drive
Keene, NH 03431
(603) 352-3812
Contact: Brian D. Farias
Regulatory Affairs Specialist

PREPARATION DATE OF SUMMARY:

December 7, 2001

TRADE NAME:

Hypodermic Needle-Pro® Insulin Syringe & Needle with Needle Protection Device

COMMON NAME:

Insulin Syringe and Needle with attached needle protection

PRODUCT CLASS/CLASSIFICATION:

Class II, 80 FMF, 21 CFR 880.5860 (Piston Syringe)

PREDICATE DEVICE(S):

K011925 Hypodermic Needle-Pro® Syringe & Needle with Needle Protection Device

DESCRIPTION:

This device is intended for injection of insulin. The needle protection device is an integral component of the device as it comes pre-attached to the needle. Once the needle/needle protection device is attached to a syringe, the collar hoop hinders removal of the needle protection device from the needle. The Needle-Pro® sheath may be adjusted relative to the needle bevel by swiveling the orange arm to the desired position. After the procedure is completed, the needle is pressed into the sheath using a one-handed technique. As the needle enters the protective sheath, the needle protection device engages and the needle is contained within the sheath. The device should be immediately disposed into a sharps container. The device is supplied with 26G and 27G needles.

INDICATIONS FOR USE:

This device is intended for injection of insulin. The needle protection device covers the needle after use to help prevent needle sticks.

TECHNICAL CHARACTERISTICS:

The proposed device is comprised of identical or similar components and materials as the predicate device. The device is sold sterile.

NON-CLINICAL DATA:

The descriptive characteristics of this device are precise enough to ensure equivalence.

CLINICAL DATA:

Not applicable

CONCLUSION:

The comparison to the predicate devices demonstrates that the proposed device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

PORTEX, INC.

Brian D. Farias
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2002

Mr. Brain E. Farias
Regulatory Affairs Specialist
Portex, Incorporated
10 Bowman Drive
Keene, New Hampshire 03431

Re: K014073
Trade/Device Name: Hypodermic Needle-Pro® Insulin Syringe & Needle with Needle Protection Device
Regulation Number: 880.5860
Regulation Name: Insulin Syringe and Hypodermic Needle with attached Needle Protection
Regulatory Class: II
Product Code: FMF
Dated: December 7, 2001
Received: December 10, 2001

Dear Mr. Farias:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B: INTENDED USE OF DEVICE

PROPOSED INDICATIONS FOR USE:

510(k) Number (if known): ~~Unknown~~ K014073

Device Name:
Hypodermic Needle-Pro® Insulin Syringe & Needle with Needle Protection Device

Indications For Use:

This device is intended for injection of insulin. The needle protection device covers the needle after use to help prevent needle sticks.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K014073